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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,340	07/30/2003	Pierre Jean F. Layrolle	04148-00030	9304

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,340	Applicant(s) LAYROLLE ET AL. S.C.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 13-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/11/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-12, in the reply filed on 8/9/2004 is acknowledged. The traversal is on the ground(s) that the groups are so linked that the examination of all groups would not be overly burdensome. This is not found persuasive because the searches for methods of coating, methods of measuring, coated products, and coating apparatuses are different, the art for each invention is different, and different issues arise during the prosecution of the various types of inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires deposition of inorganic ions and passage of a coating solution through a reactor wherein the reactor has a partition to retain the bioactive agent in the reactor. This claim is unclear. It is not clear what is being retained by the reactor and what is passing through the reactor. Inorganic ions on medical devices are known to act as

"bioactive agents", therefore the inorganic ions and bioactive agent may be the same material in this claim. The claim does not make clear, in its body, if the inorganic ions and bioactive agent are meant to be different materials. Examiner suggests that elements of the preamble be incorporated into the body of the claim and that the claim be clarified to recite a medical device substrate and a coating step, along with clarification of the materials which coat the substrate and which materials pass through versus remain within the reactor. The claim as currently written is interpreted only to require that a solution, not necessarily one containing any deposition agents, pass through, but that a bioactive agent of inorganic ions or other material is retained in a reactor.

In claim 7, HEPES and Tris should be spelled-out or, if trademarks, described in their generic terminology

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Layrolle et al. (6,207,218).

Layrolle teaches depositing inorganic ions from a stream of bubbled carbon dioxide (col. 3, line 63; throughout). The carbon dioxide/water solution acts as Applicant's "coating solution" because it acts to deposit or coat the inorganic ions by affecting the pH. This solution is passed through the reactor as it bubbles out. The inorganic ions act as the bioactive agent (col. 4, line 55), which are retained by a partition of the reactor (see Figure 1 in which the walls of the container itself retain the inorganic ions in the reactor).

Layrolle teaches the use of plural inorganic layers (col. 8, line 52). Each layer may be applied using the bubbled carbon dioxide, providing the acidic solution claimed by Applicant, which would redissolve the inorganic salts and obtain a coating of the inorganic bioactive agent.

Layrolle teaches the concentrations of claims 7 and 12 (col. 9, lines 5-7).

Layrolle teaches coating medical substrates of the materials of claim 8.

Layrolle teaches the use of other bioactive agents other than inorganic ions, such as peptides, growth factors, and bone morphogenic proteins (col. 9, lines 54-57), all of which would be "retained" in the reactor as the carbon dioxide is bubbled through.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Salviato is cited for teaching the membrane of Applicant for use

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in depositing solutes within the reactor while streaming solvent therethrough. The solutes may be bioactive, however Salviato fails to teach inorganic solutes.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kolb Michener
Patent Examiner
AU 1762
9/1/2004